UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,213	05/30/2006	Nicole Pauloski	5185	7944

35969 7590 07/24/2008

Barbara A. Shimei
Director, Patents & Licensing
Bayer HealthCare LLC - Pharmaceuticals
555 White Plains Road, Third Floor
Tarrytown, NY 10591

EXAMINER	
BAUSCH, SARAE L	
ART UNIT	**PAPER NUMBER**
1634	

MAIL DATE	DELIVERY MODE
07/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,213	PAULOSKI ET AL.	
	Examiner	Art Unit	
	SARAE BAUSCH	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 12-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to applicants correspondence mailed 04/07/2008. The amendment to the claims mailed 04/07/2008 has been entered

Election/Restrictions

2. Applicant's election with traverse of group III, claim 11 and SEQ ID No. 1-19 in the reply filed on 04/07/2008 is acknowledged. The traversal is on the ground(s) that the claims have been clarified that one or more genes or gene products whose expression is analyzed by methods of the invention are regulated by histone deacetylase and the asserted prior art does not teach or suggest the analysis of genes that is regulated by histone deacetylase each of the claims contain a corresponding special technical feature. This is not found persuasive because expression of TP and DPD genes are regulated by histone deacetylase and thus the prior art of Terashim et al. does teach the special technical feature of the claims. Additionally, Dan et al. teaches the expression analysis of cyclin B1 which is also regulated by histone deacetylase and thus provides additional evidence that the special technical feature is not a contribution over the prior art.

The response assert that the sequences are not structurally distinct compounds as each of the genes are markers of tumorgenesis and linked to HDAC regulation. This response has been thoroughly reviewed but not found persuasive. Each of the genes are structurally distinct chemical compounds, each sequence encodes a different protein with different functional attributes and thus are structurally distinct.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-8, 12-22 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/07/2008.

4. Currently, claims 9-11 are under examination. The specific combination of SEQ ID No. 1-19 is under examination for claim 11.

Specification

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112- Second Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is vague and indefinite. Claim 9 is drawn to a method for identifying a compound useful for the treatment of cancer, however the final process step is analyzing the level of expression of one or more genes and/or gene products in a cell or tissue sample subsequent to treatment with the compound; wherein a variation in the expression level of the gene and/or gene product is indicative of drug efficacy and wherein the one or more gene or gene products are regulated by histone deacetylase. Accordingly the claims are ambiguous because the variation in the expression level of the gene is indicative of drug efficacy however drug

efficacy does not relate nor encompass identification of a compound useful for treatment of cancer and therefore it is not clear that a variation in the expression level of a gene and/or gene product is indicative of drug efficacy will *necessarily* result in identifying a compound useful for the treatment of cancer. Therefore, the limitation in the preamble is not recited in the process steps, the metes and bounds of the claim are vague and indefinite, and it is unclear if one necessarily accomplishes what is intended from the method by practicing the recited method step(s).

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and the breadth of the claims

The claims are drawn to a method for identifying a compound useful for the treatment of cancer by analyzing the level of expression of one or more genes in a cell or tissue sample prior to treatment with the compound, analyzing the level of expression of one or more genes in a cell or tissue sample subsequent to treatment with the compound; wherein a variation in the expression level of the gene is indicative of drug efficacy and wherein the genes are regulated by histone deacetylase. The claims are further drawn to a compound that is a histone deacetylase inhibitor and genes consisting of SEQ ID No. 1-19.

The rejected claims encompass analysis of any type of cancer, any cell or any tissue sample, and any compound that modulates expression. The rejected claims encompass any modulations in expression, increase or decrease in gene expression levels. The rejected claims encompass analysis of any gene that is regulated by histone deacetylase. The nature of the claims requires the knowledge of a correlation that a compound will modulate expression levels of any gene regulated by histone deacetylase in any cell type or any tissue sample and are correlated to the treatment of cancer.

The invention is in a class of inventions which the CAFC has characterized as "the unpredictably arts such as chemistry and biology" (Mycolgen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Federal Circuit 2001)).

Guidance in the Specification and Working Examples

The specification asserts that the expression profile of SEQ ID No. 1-19 demonstrate altered expression following exposure to a drug, particularly a histone deacetylase inhibitor (see paragraph 7). The specification asserts that the present invention is a method for screening the effects of a drug on a tissue or cell sample by analyzing the expression before and after treatment and a variation in expression is indicative of drug efficacy (see paragraph 13-14). This encompasses that any variation in expression in indicative of drug efficacy in any gene that is regulated by histone deacetylase, however the specification does not teach nor provide any guidance that any variation, increase or decrease in expression level of any gene regulated by histone deacetylase in any cell or tissue sample is correlative to drug efficacy for the treatment of any type of cancer.

The specification teaches that cancer includes but is not limited to solid tumors, such as breast, respiratory tract, brain, reproductive organs, digestive tract, urinary tract, eye, neck, their distant metastases and also includes lymphomas, sarcomas, and leukemias (see para. 48-49), however the specification does not provide any guidance or teach that a drug that modulates expression of gene regulated by histone deacetylase (HDAC) is indicative of a compound useful in treating any of the cancers specified.

The specification asserts that level of expression refers to the level of mRNA (see paragraph 69). The specification asserts that the methods are for designing and optimizing drugs for cancer by comparing the expression level of one or more gene characteristic of small molecule efficacy following incubation with a disease cell of cancer or similar cell with test compound. The specification asserts that the efficacy of the compound may be tested in vitro and in vivo assays and in animal models. The specification asserts that normalization of the

expression of one or more genes is indicative of efficiency of the compound for treating cancer (see paragraph 131-132). However the specification does not teach any change in expression level of genes that would predictably correlate that the efficiency of a compound. The specification does not teach analysis of any drug that modulates expression levels of any gene regulated by histone deacetylase, much less SEQ ID No. 1-19 that would provide guidance to the skilled artisan to predictably determine if a change in expression in SEQ ID No. 1-19 or any gene regulated by histone deacetylase would indicate efficacy of the test compound or drug.

The specification teaches that tumor cells of the same type may not show uniformly increased expression of individual oncogenes or decreased expression of tumor suppressor genes and there may be varying levels of expression of given type of cancer further emphasizing the need for a battery of tests rather than a single test (see paragraph 171). Thus the specification is teaching the unpredictability of correlating the expression level variations of any one gene in a cell or a tissue sample with drug efficacy as the expression level between tumor cells is not uniform thus it would be unpredictable to determine if the expression level variation is due to the variation among tumor cells or the drug efficacy.

The specification demonstrates a working example in which human colon cancer cells were implanted in each mouse. The specification teaches that the vehicle used for the HDAC inhibitor was 12.5% ethanol, 12.5% cremafor EL, water or saline and dosing was intravenous at 25 mg/kg once a day for 3 days. The specification asserts that table 1 describes genes that were up or down regulated greater than or equal to two fold in the HDAC inhibitor treated HCT-116 cells relative to vehicle treated cells. Table 1 provides the change in expression for the 19 genes at 3, 6, and 24 hr change in 2 samples. The following is unclear from the working example. The

example does not teach or provide guidance on the HDAC inhibitor that was used nor provide data that statistically correlates the expression level of each gene with drug efficacy. The examples does not teach if the treatment was effective, for example did the HDAC inhibitor reduce the tumor, reduce the rate of growth of the tumor, etc.. Additionally, the specification asserts that genes that were up or down regulated greater than or equal to two fold are listed in table 1 however three of the genes are below a two fold change in expression. Additionally, its unclear how one could use SEQ ID No. 1-19 to analyze the treatment of any cell type as table 1 demonstrates that treatment at day 3 after 3 hours, 6 hours, and 24 hours the expression level of some of the genes drastically changes and thus changes appear to depend on the hour and day the expression level is analyzed. For example, the expression levels of SEQ ID No. 2, 7, 10, 11, 14, 15, 17, 19 vary drastically depending on the hour in which analyzed on day 3. Additionally, the specification does not provide any indication that the HDAC inhibitor reduced the tumor in the mice and thus there is no guidance that the expression level that were measured are indicative of drug efficacy. Additionally, the specification does not provide statistically significant data that would allow the skilled artisan to predictably correlate the expression level of SEQ ID No. 1-19 with drug efficacy. The specification provides no indication as to whether the expression level of each of these genes is significant such that the skilled artisan would be able to predictably correlate the results with the efficacy of drug. The specification provides no guidance on how to determine if a compound would be effective in treatment of cancer as the specification does not provide any examples or any guidance with HDAC inhibitors or any compound that modulates expression and is indicative of treatment of cancer.

The following is unclear from the guidance in the specification. The specification does not provide any teaching or examples on the specific connection between the expression levels of SEQ ID No. 1-19 and the status of the cell, for example if the cell or tissue is healthy or solid tumor, etc. For example, are the expression values in table 1 indicative of all cancer cells that are treated with any HDAC inhibitor or will the expression level of the genes of SEQ ID No. 1-19 vary upon the type of cell, tissue, and type of compound screened? Furthermore, there is no guidance on the time dependence of treatment and expression level, based on the working example it appears that expression is dependent on time of exposure to the drug. The specification provides no teaching of how the application of a compound could or does modulate the expression level of SEQ ID No. 1-19 in any cancer cell, any cell, or any tissue sample. For example, if a compound was applied to a solid breast cancer cell, the skilled artisan would not be able to predictably correlate the expression value of SEQ ID No. 1-19 with the ability of the compound to treat cancer as the specification does not provide any data in which treatment of cancer with a drug was effective and this effectiveness is depicted in variation in expression levels of SEQ ID No. 1-19 in breast cancer cells.

The specification envisions hypothetical situations where "any" compound, could treat any type of cancer in any cell or any tissue sample and the expression level of any gene that is regulated by histone deacetylase will be modulated when the compound is effective in treatment. The specification appears to be conceiving of possible scenarios where the expression level could be modulated by the use of "any" compound and that these results could indicate treatment of any type of cancer, however, it is unclear how one of skill in the art would determine the level of expression necessary to determine if "any" compound has the ability to treat any cell or tissue

sample by analyzing the level of expression in any gene that is regulated by histone deacetylase. The specification clearly teaches that expression levels of genes vary among different tumor cells, thus it is unpredictable based on the guidance in the specification to determine if any compound is effective in treatment of cancer based on the expression analysis of genes in any cell or any tissue sample.

The unpredictability of the art and the state of the prior art

While the state of the art and level of skill in the art with regard to detection of a gene expression in a sample is high, the level of unpredictability in associating any particular expression level with a phenotype is even higher. The level of unpredictability is demonstrated by the prior art, the post filing art, and the instant specification.

Shalon et al. (US 2001/0051344 A1 Dec 13, 2001) teach that due to variations in genetic make-up of unrelated individuals in a heterogeneous society, differences in the expression of a gene between any two individuals may or may not be significant (see page 10, paragraph 0155). Shalon et al. further teach that the larger the number of individuals tested, the more significant the remaining differences in gene expression become and samples from at least 5 and preferably 20-50 different test individuals are assayed to obtain statistically meaningful data showing a statistical elevation or reduction in report levels when compared to control levels (see page 10, paragraph 0156). Sharlon et al. teach that the test average pattern is compared with a control average pattern on a microarray to identify test genes which show significantly, typically at least 2 fold and up to 100 fold or more, increase or decrease in gene expression level with respect to control levels for the same gene (see page 10, paragraph 0158). Post filing art, Kroese et al.

(Genetics in Medicine, vol 6 (2004), p. 475-480) teach genetic tests are heterogeneous in nature and the exact characteristics of a particular genetic test to be evaluated must be tightly defined. Kroese et al. teach that a particular genetic condition may be caused by more than one gene and these variations may be due to deletions and insertions not detected by routine sequence methods. (see page 476, 2nd column, last paragraph). Kroese et al. teach that genetic test is shorthand to describe a test to detect a particular genetic variant for a particular disease in a particular population and for a particular purpose and that it should not be assumed that once the characteristics of a genetic test are evaluated for one of these reasons that the evaluation will hold or be useful for other purposes and all measures of the test performance should be presented with their 95% confidence intervals (see page 477, 1st column, 1st and 2nd full paragraph). Kroese et al. teach that the limitations of our genetic knowledge and technical abilities means that for the moment there are likely to be gaps in the information needed to complete a thorough evaluation of many genetic tests (see page 479, 2nd column, last paragraph). Additional post filing art reveals that most gene association studies are typically wrong. Lucentini (The Scientist, 2004, Vol 18, page 20) teach that it strikingly common for follow-up studies to find gene-disease associations wrong (see page 2, 1st paragraph). Lucentini teaches that two recent studies found that typically when a finding is first published linking a given gene to a complex disease there is only roughly a one-third chance that the study will reliably confirm the finding (see page 2, 3rd paragraph). Lucentini teaches that bigger sample sizes and more family-based studies, along with revising statistical method, should be included in the gene association studies (see page 3, 2nd paragraph). Based on the data presented in the specification and the prior art teachings, it is unpredictable to correlate genes regulated by histone deacetylase or specifically SEQ ID No. 1-

19 with identifying a compound that is useful for treatment of cancer in a cell or tissue sample using any compound.

Ross et al. (Am J Clin Pathol, 2005, 124 (suppl1) S29-41) teach that anticancer drugs show limited efficacy in as many as 70% of treated patient. Ross et al. teach despite the potential of pharmacogenomics as a novel tool there are technical challenges that need to be solved before wide clinical application are substantial. Ross et al. teaches there is a lack of standardization of pharmacogenomics. Ross et al. teach that the type of tissue sampling clearly has a major impact on profiling results because the transcriptional profiles are composites of mRNA of all tissue components of the biological sample. Ross et al. teach that microdissected tissue, fine needle aspiration biopsy, core need biopsy all give significantly different transcription profiles from the same tumor and thus results generated might only be valid for the microarray platform and tissue sampling technique used (see pg. S35, 1st column, last paragraph). Ross et al. teach that during the next several years the ability of this approach to treat newly diagnosed cancer will be tested on large scale (see pg. s37, 1st column, 1st paragraph). Thus, even post filing art suggests there is considerable unpredictability in analyzing any one tissue sample or cell for gene expression profile for modulation in expression upon treatment with a drug or compound.

Quantity of Experimentation

Given the lack of guidance in the specification with regard to association of expression level of a gene in a cell upon treatment with a compound in "any" cell with "any" gene regulated by deacetylase histone along with the evidence in the art that demonstrates that associating expression of gene with phenotypes is unpredictable, the quantity of experimentation in this area is extremely large. The skilled artisan would have to perform an extremely large study and

include different populations and familial studies for each type of cancer in each cell and tissue sample to determine if in fact there was either an association between expression level in the cell and treatment with a drug and the results of such a study are unpredictable, as evidence by the post filing art. In the instant case, it would be unpredictable as to whether or not any compound would be responsible for treating cancer and modulating the expression level of genes regulated by deacetylase histone. In order to practice the invention as broadly as it is claimed, the skilled artisan would have to perform an extremely large amount of trial and error analysis in a large study to determine if such expression levels would predictable determine drug efficacy in all or any cancer cell or tissue. Given the lack of guidance in the specification and the post filing art with respect to accurately testing genetic diseases, such analysis is replete with unpredictable experimentation and is considered undue.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Dan et al. (Biochemical and Biophysical Research Comm. 2001 280:861-867).

Dan et al. teach human lung cancer cells were exposed to adriamycin (histone deacetylase inhibitor, claim 10). Dan et al. teach expression level was analyzed for mRNA from adriaymcin treated A549 cells and teach expression levels analyzed for mRNA in A549 cells not treated with

adriaymcin cells (see array screening, pg. 862). Dan et al. teach expression level of cyclin B1 was reduced upon treatment with adriaymcin cells (see table 1). Thus, Dan et al. teach analyzing expression level of one or more gene in a cell prior to treatment with a compound, analyzing expression level of one or more gene in a cell subsequent to treatment with the compound wherein variation in the expression level is indicative of drug efficacy and gene is regulated by histone deacetylase, as cyclin B1 is regulated by histone deacetylase. It is noted that the claim does not require that the same cell that was analyzed for gene expression prior to treatment is the same cell that is analyzed subsequent to treatment. The claim merely requires that "a cell or tissue sample" is analyzed prior to and subsequent to treatment.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 9-11 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-8 of copending Application No. 10/581125. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 9 falls entirely in scope of claims 6-8 of '125. Specifically claims 6-8 of '125 recite a method for identifying a compound useful for treatment of cancer by analyzing expression of cell or tissue sample prior to and subsequent to treatment with a compound wherein a variation is indicative of drug efficacy. Claims 7-8 recite where in the gene is stamiocalcin. The instant claims recite a method for identifying a compound useful for treatment of cancer by analyzing expression of cell or tissue sample prior to and subsequent to treatment with a compound wherein a variation is indicative of drug efficacy wherein the genes are regulated by histone deacetylase. It is noted that any gene in which the expression levels are changed or any gene involved in cancer will be regulated by histone deacetylase, thus the claims overlap in scope. Additionally, claims 7-8 of '125 specifically recite where in the gene is stamiocalcin and stamiocalcin is regulated by a histone deacetylase. Thus claims 7-9 fall entirely in scope of instant claims 9-11.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Sarae Bausch/
Primary Examiner, Art Unit 1634